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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/692,031

10/23/2003

William F. Crismore

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41577

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03/09/2009

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP  
111 MONUMENT CIRCLE, SUITE 3700  
INDIANAPOLIS, IN 46204-5137

EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

03/09/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@uspatent.com  
GMercer@uspatent.com  
Karla.Dirks@Roche.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/692,031	<b>Applicant(s)</b> CRISMORE ET AL.	
	<b>Examiner</b> Lyle A. Alexander	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 68-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### ***Reissue Applications***

The reissue oath/declaration filed with this application is defective because it fails to contain the statement required under 37 CFR 1.175(a)(1) as to applicant's belief that the original patent is wholly or partly inoperative or invalid. See 37 CFR 1.175(a)(1) and see MPEP § 1414. Applicants' must file a new declaration that reflects all of the amendments to date. The 12/21/07 declarations are insufficient because they do not acknowledge all of the amendments (i.e. the 12/27/07 amendments) and are not signed by all of the inventors.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification, as described in USP 5,997,817, does not teach a "fill line" to determine the proper amount of sample. Rather, it appears the patent teaches an area where the user can see if the proper amount of sample is present.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 68-104 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 122-155 of copending Application No. 10/409,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because all are directed to an indistinguishable invention of test strip comprising a capillary channel, electrodes, an edge to receive the sample and a reagent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 68-104 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Diebold et al.(USP 5,437,999).

Diebold et al. teach the same structure of a device with cut out portions, a vent and reagents associated with the electrodes.

Claims 68-104 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hodges et al. (USP 5,942,102) or Hodges et al. (USP 6,174,420)

The Hodges et al. references teach an electrochemical test device for the determination of glucose in blood. Hodges ('102) teaches a working electrode(2), a counter electrode(16) and a dried reagent of GOD and ferrocyanide. The device is assembled between two layers and notched on opposite sides to admit the sample by capillary and allow air to escape out of the other side (see column 5 lines 3-10). The claimed *"atleast working and counter electrodes"* have been read on the taught **working electrode(2) and counter electrode(16)**. The claimed *"test reagent"* has been read on **the taught dried reagent of GOD and ferrocyanide**. The claimed *"capillary channel and a vent in fluid communication with a sample application port ... the edge defining an indentation"* has been read on the taught **one notch side admits the sample by capillary action and air to escapes from the opposite notch (e.g. the opposite notch has been read on the vent)**. Hodges('420) is applied in the identical manner.

Claims 68-104 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Charlton et al. (USP 5,798,031).

Charlton et al. in figure 1 an electrochemical glucose sensor. **Electrodes(38 and 39)** have been read on the claimed *"atleast working and counter electrodes"*. The **reagent layer(40)** has been read on the claimed *"test reagent"*. The claimed *"capillary*

*channel and a vent in fluid communication with the capillary channel ... with a sample application port*" has been read on the taught **concave space(48) that admits the sample to a capillary action and vent(50).**

Claims 68-104 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ikeda et al. (USP 5,575,895) or Yoshioka et al. (USP 5,264,103).

Ikeda et al. teach an electrochemical device for the determination of glucose in a blood sample. Insulating base plate(1) is provided with conductors(2,3), **working electrode(4) and counter electrode(5)** that have been read on the claimed "*at least working and counter electrodes*". Reaction **layer(7)** is in contact with the electrode system has been read on the claimed "*test reagent*". Slotted spacer(8) provides a notch for sample acquisition and is in communication with channel(12) and vent(13) has been read on the claimed "*capillary channel and a vent in fluid communication with the capillary channel ... with a sample application port*". Yoshioka et al. has been applied in the identical manner.

Claims 68-104 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by  
Galen et al.

Galen et al. teach a test strip having a sample application port (20) along an edge having notch(19) that assures proper alignment in the detector. Column 10-12 teach a fructosamine multiplayer test device where the multiple layers all have the same notch cut out. Column 1 lines 30 + teach use of radiation blocking layers and contamination prevention layers which have been read on the claimed "substantially "

opaque portion" and the "transparent window" respectively.

Claims 68-104 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Seshimoto et al. (USP 4,684,445), Columbus (USP 4,473,457) or Ikeda et al. (USP 5,798,031).

These references all teach an electrochemical test device with a transparent and opaque portions, a conductive track, vents and a sample application port.

### ***Response to Arguments***

Applicant's arguments filed 12/21/07 have been fully considered but they are not persuasive.

Applicants' state the original patent supports the claimed "fill line" limitations because a line of demarcation is taught. The Office has interpreted the evidence presented as teaching the user can observe the filling of the capillary. The Office has not been convinced this evidence supports a line of demarcation or a "fill line" and maintains the claims are properly rejected under 35 USC 112 first paragraph.

Applicants' state Charlton et al., Seshimoto et al., Columbus and Ikeda et al. all fail to teach the claimed "fill line". The Office does not believe Applicants' have support for such an amendment. Even if Applicants' could show support for "fill line", the Office would maintain it is notoriously well known in the analytical art to provide a fill line to let the user know if enough fluid sample has been added. All of these reference could be rejection under 35 USC 103 stating incorporation of a fill line it within the skill of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander  
Primary Examiner  
Art Unit 1797

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